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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,815	10/18/2001	Wolfgang Muhlbauer	GLAWE-06599	5359

7590 08/30/2005

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EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/041,815

Applicant(s)

MUHLBAUER ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

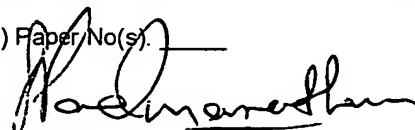
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 12, 14-25  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.



**SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER**

Continuation of 11. does NOT place the application in condition for allowance because: of the reasons of record. Applicant has argued that the rejection of record does not address the claim limitation "increasing alkalinity." In response Examiner states that such issue was addressed in both previous Non-Final and Final Rejections. Nevertheless, Example hereby elaborates on Applicant's position. First, Applicant has not provided any competent reasoning as to why the use of the composition of Fues, which meets all elements of the instantly employed composition, does not meet the limitation of the instant claims. Fues' composition contains all elements of the instantly employed composition. (see Non-Final Rejection filed on 11/17/2004 at page 3) The rejection stated that functional alkalinity limitations are met because all elemental components of the instant composition is described by Fues (see Id). Nevertheless, Clark was used to show that it would have been obvious to one of ordinary skill in the art at the time of invention to expect collagen stimulation subsequent to use of Fues' composition because at least the presence of lactic acid or its salts following the use of Fues composition will result some degree of stimulation of collagen synthesis. Applicant then in the Response filed on 3/18/2005 argued that collagen stimulation can not occur by Fues composition because they don't contain lactic acid. Examiner then replied in the subsequent Final Rejection filed 6/15/2005, that these line of arguments are not material to the scope of the claims, because all elements of the composition described by Fues teach the same elements of the instant composition. Clark was only presented to show that there is a presumption of improving collagen stimulation upon formation of Lactic Acid. However, nowhere in the Final Rejection, or in Fues teachings, is there any statement to the effect that Fues Compositions leads to a decrease alkalinity at the site of bone wound.

Applicant now argues that if lactic acid is present in Fues' compositions they decrease the pH to promote collagen regeneration, while the Examiner argues that lactic acid in a composition could be used to stimulate collagen regeneration. (see Arguments at page 4). In response, Examiner states that Applicant's characterization of the rejection is incorrect. Therefore, Examiner does not find Applicant's arguments persuasive because Examiner believes they are collateral to the central issue of the pending rejection which is whether the use of Fues' formulation as a dressing for the bone would render the instant claims obvious. Examiner has previously addressed in the Final Rejection that the claimed invention are not limited to lactic acid, nor do they exclude the use of lactic acid. Thus, applicant's arguments are not commensurate with the scope of the claims. (see Final Rejection at page 4). The teachings of Clark was supplemental to Fues to show that at least the use of Fues would have provided an expectation of success for causing stimulation of collagen synthesis. Such expectation of success was based on the fact that Fues composition can release lactate or lactic acid, and lactic acid had been associated with collagen synthesis at local levels. Note that the rejection states that "the ordinary skill in the art would have had a reasonable expectation of observing a local stimulation of collagen regeneration at the site where FUES' COMPOSITION would have been applied. (see Id.) Therefore, there is absolutely no teachings in the Fues or in the reasoning of Final Rejection towards the necessity of Lactic Acid to cause a decrease in local pH thereby causing collagen regeneration. Furthermore, Applicant has not provided any evidence that Fues compositions do not cause stimulation of collagen or even do not cause an elevation of alkalinity at the local level. Fues composition for example can contain up to 20% of Ca Glycolate, up to 20% Ca Lactate and up to 20% Hydroxyapatite (see col 8-12). Even if one microgram of lactic acid is generated at the local level following its use; according to Clark, such lactic acid can stimulate collagen regeneration within the scope of the instant claims. Such conclusion is not the same as to say FUES COMPOSITION comprising Ca Glycolate, Ca Lactate and Hydroxyapatite decreases local alkalinity subsequent to its administration. Furthermore, applicant has provided no evidence showing such effects. Thus, Applicant's arguments are not found persuasive. The fact remains that Fues compositions meet all elements of the composition instantly employed. Fues uses his composition as bone dressing. There is a reasonable expectation of success that Fues composition improve collagen synthesis as reasoned by Clark. Thus, absent a competent showing or reasoning, the claims are obvious in view of the combined teachings of the references. Applicant's arguments do not address this issue and are collateral to the central reasoning of the rejection.

Applicant's request for an interview has been noted. However, the prosecution on the merits of the claims are closed at this time and there is no unresolved substantive issue at this time. Applicant may contact Examiner to schedule an interview to further discuss the claims at anytime.